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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,687	11/21/2001	Luisa Iruela-Arispe	1488.107000D/EKS/CML	9708

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HUMAN GENOME SCIENCES INC
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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

MC

Office Action Summary

Application No.

09/989,687

Applicant(s)

IRUELA-ARISPE ET AL.

Examiner

Karen A. Canella

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3, 5-7 and 9-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 5-7, 15-20, 27-32 is/are rejected.
- 7) ☐ Claim(s) 9-14 and 21-26 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1, 2, 5 and 6 have been amended. Claims 1-3, 5-7 and 9-32 are pending and under consideration.
2. Sections of Title 35, U.S. Code, not found in this action can be found in a prior action. 1-3, 5-7, 15-20 and
3. The rejection of claims 27-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the following reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to methods reliant on a genus of METH2 polypeptides which minimally comprise single domains of the METH2 polypeptide: a polypeptide comprising the metalloprotease domain of METH2, amino acids 214 to 439 in SEQ ID NO:4; a polypeptide comprising the disintegrin domain of METH2, amino acids 440 to 529 in SEQ ID NO:4; a polypeptide comprising the first TSP-like domain of METH2, amino acids 530 to 583 in SEQ ID NO:4; a polypeptide comprising the second TSP-like domain of METH2, amino acids 837 to 890 in SEQ ID NO:4; a polypeptide comprising amino acids 280 to 606 in SEQ ID NO:4; a polypeptide comprising amino acids 529 to 548 in SEQ ID NO:4.

The genus of polypeptides is highly variant because said polypeptide need only minimally comprise a fragments of SEQ ID NO:4. The claims do not limit the polypeptides by functional attributes. The specification provides a written description of SEQ ID NO:4, mature forms of SEQ ID NO:4, and a variant of SEQ ID NO:4 having an additional 18 amino acids on the carboxyl terminus. This disclosure fails to adequately describe the claimed genus because the genus contains molecules which differ widely in structural attributes as well as functional attributes from SEQ ID NO:4. One of skill in the art would reasonably conclude that applicant was not in possession of the claimed genus.

4. Applicant has amended claims 1, 2, 5 and 6 to recite the limitation 'wherein said polypeptide has METH2 activity' in order to limit the functional attributes of molecules which

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fall within the genus of METH2 polypeptides claimed. This has been considered but not found persuasive. The specification lacks a limiting definition for "METH2" activity which could serve to as a functional limitation for the claimed genus of METH2 polypeptides. The specification states on page 117, lines 22-31:

By "a polypeptide having METH1 activity" is intended polypeptides exhibiting METH1 activity in a particular biological assay. For example, METH1 protein activity can be measured using the chorioallantoic membrane assay (Iruela-Arispe et al., Thrombosis and Haemostasis 78(1):672-677 (1997)) or the cornea pocket assay (Tolsma et al., J. Cell. Biol. 122:497-511 (1993)), both described in Example 4, below. By "a polypeptide having METH2 activity" is intended polypeptides exhibiting METH2 activity in a particular biological assay. For example, METH2 protein activity can also be measured using the chorioallantoic membrane assay (Iruela-Arispe et al., Thrombosis and Haemostasis 78(1):672-677 (1997)) or the cornea pocket assay (Tolsma et al., J. Cell. Biol. 122:497-511 (1993)).

Thus the specification is suggesting that the ability to stimulate or inhibit angiogenesis can be measured in the two described assay systems. However, the ability to measure an activity in an assay is not a limiting definition for the genus of compounds claimed.

5. Claims 9-14 and 21-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. All other rejection and objections as set forth or maintained in the previous Office action are withdrawn.

7. It is noted that in the prior action, the examiner states that residues 235-490, 545-598, 841-894, 895-934, 536-613 and 549-563 of the instant SEQ ID NO:4 were encompassed by the disclosure of Klonowski et al. This was a typographic error. The examiner had intended to relay that said residues of the instant SEQ ID NO:2 rather than SEQ ID NO:4 were encompassed by the disclosure of Klonowski et al. However, applicant recognized the oversight and canceled the appropriate subject matter drawn to fragments of SEQ ID NO:2.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

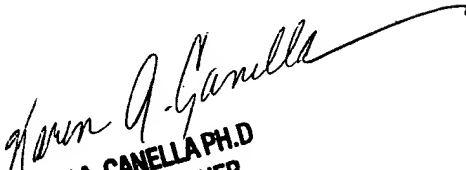
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

9/6/2005


KAREN A. CANELLA PH.D
PRIMARY EXAMINER